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S/N 09/820,198

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jackie R. Bickenbach et al.

Examiner: Beena Puri, Ph.D

Serial No.: 09/820,198

Group Art Unit: 1633

Filed: March 28, 2001

Docket: 875.029US1

Title: METHODS TO PREPARE AND USE EPIDERMAL STEM CELLS

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RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Restriction Requirement mailed December 19, 2001, Applicant provisionally elects, with traverse, the claims of Group I (claims 1-27), directed to a method to prepare isolated mammalian epidermal stem cells, comprising: separating a population comprising epidermal stem cells from a population of mammalian epidermal cells, and isolating a substantially pure population of epidermal stem cells from the population of epidermal stem cells; and a method to prepare isolated mammalian epidermal stem cells, comprising: contacting a first population of mammalian epidermal cells comprising epidermal stem cells with a first agent that is retained by viable cells and a second agent that is retained by non-viable cells, and separating the population into a population of viable epidermal stem cells and at least one population of cells that does not comprise epidermal stem cells. Reconsideration of the Restriction Requirement, in view of the remarks presented below, is respectfully requested.

The Restriction Requirement is traversed on the basis that the inventions are so closely related they cannot be properly considered independent and distinct within the statutory meaning of 35 U.S.C. § 121. For example, claims directed to methods to prepare isolated mammalian epidermal stem cells and isolated epidermal stem cells prepared by the methods (claims 1-27; Group I) are clearly related to claims directed to a method of using the isolated epidermal stem cells prepared by those methods in which the isolated epidermal stem cells are transformed with exogenous nucleic acid and transformed epidermal stem cells identified (claims 28-32; Group II), or are contacted with a substrate so as to yield a tissue (claims 33-36; Group III).

Moreover, the Restriction Requirement is also traversed on the basis that Restriction Requirements are optional in all cases. M.P.E.P. § 803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits,

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even though it arguably may include claims to distinct or independent inventions. M.P.E.P. § 803. In light of this, it is submitted that Applicant should not be required to incur additional costs associated with the filing of multiple divisional applications in order to obtain protection for the claimed subject matter. For example, the claims of Groups I, II and III can efficiently and effectively be searched in a single search, as the claims in these groups are generally directed to methods to prepare isolated mammalian epidermal stem cells (Group I) and methods of using the isolated epidermal stem cells, e.g., to yield transformed epidermal cells (Group II) or to prepare a tissue *in vitro* (Group III). Thus, it is evident that the claims in Groups I, II and III are closely related and can be efficiently and effectively searched in a single search.

Further, the claims in Group I include claims directed to isolated epidermal stem cells prepared by the claimed methods (claims 15 and 27), and claims directed to methods of using those cells, for example, to prepare transformed epidermal stem cells (Group II), to prepare a tissue *in vitro* (Group IV), and to prepare a chimeric non-human mammal (Group V), are linked to the isolated epidermal stem cells of claim 15 or 27. Thus, upon allowance of claims 15 or 27 in Group I, the restriction requirement as it relates to claims linked to claims 15 or 27 should be withdrawn. M.P.E.P. 809.03.

Therefore the Restriction Requirement is properly traversed, and reconsideration is respectfully requested.

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The Examiner is invited to contact Applicant's Representatives at the number given below if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

Respectfully submitted,

JACKIE R. BICKENBACH ET AL.

By their Representatives,

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Date January 22, 2002 By Janet E. Embretson  
Janet E. Embretson  
Reg. No. 99,665

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 22nd day of January, 2002 (Tuesday following a federal holiday).

Candis B. Buending  
Name

Signature

Candis B. Buending